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#9
Appeal Brief
S. Byers
1/28/03

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Inventor: W. Stan Wilson

Serial No.: 10/021,914

Filed: December 12, 2001

For: CATHETER ASSEMBLY AND
METHOD FOR POSITIONING THE SAME
AT A BIFURCATED VESSEL

Group Art No.: 3763

Examiner: Thompson, Kathryn L.

Docket No.: ACS 59175 (2160D)

January 14, 2003

APPELLANT'S BRIEF ON APPEAL

BOX AF
Commissioner for Patents
Washington, D.C. 20231

INTRODUCTION

The present invention relates to a catheter assembly and method for positioning the same at a bifurcated vessel. The delivery assembly of the present invention has the novel feature of containing two guide wire lumens in a single catheter to prevent wire wrapping and crossing of the wires. Additionally, the invention provides for a clip or retaining member for holding the wires at their

proximal ends outside of the patient, thus helping to prevent wire wrapping, wire crossing, and confusion when identifying and manipulating the two wires.

Appellant is filing a Notice of Appeal concurrently herewith, from the final Office action dated August 28, 2002. This appeal centers on whether the claimed invention is anticipated by Penn et al. (U.S. Pat. No. 6,033,435) under 35 U.S.C. § 102(b). Appellant has presented strong arguments to traverse the rejection, establishing that the Penn et al. reference does not disclose the invention as claimed.

The present application was filed on December 12, 2001, and is a division of U.S. Serial No. 09/465,101 filed on December 16, 1999.

1. **REAL PARTY IN INTEREST**

All rights to this application have been assigned to Advanced Cardiovascular Systems, Inc., 3200 Lakeside Drive, Santa Clara, California 95052. Thus, the real party in interest is Advanced Cardiovascular Systems, Inc., the Appellant herein.

2. **RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

3. STATUS OF CLAIMS

Claim 10 is pending and is the only claim appealed. A copy of the claim appealed is attached hereto as Exhibit 1.

Claim 10 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Penn et al. (U.S. Patent No. 6,033,435, a copy of which is attached hereto as Exhibit 2).

4. STATUS OF AMENDMENTS

Preliminary Amendment Dated December 12, 2001 (a copy of which is attached as Exhibit 3)

In a Preliminary Amendment, filed concurrently with this application on December 12, 2001, Applicant canceled claims 1-9, and claim 10 remained pending.

First Office Action Dated May 9, 2002 (a copy of which is attached as Exhibit 4)

In a first Office action dated May 9, 2002, the Examiner rejected claim 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,462,530 to Jang.

Amendment Dated August 5, 2002 (a copy of which is attached as Exhibit 5)

In an Amendment dated August 5, 2002, Applicant amended claim 10 and provided arguments to overcome the 35 U.S.C. § 102(b) rejection.

Final Office Action Dated August 28, 2002 (a copy of which is attached as Exhibit 6)

In a final Office action dated August 28, 2002, the Examiner rejected claim 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,033,435 to Penn et al. The Examiner stated that the Applicant's previous amendment necessitated the new grounds of rejection presented in this Office action, and therefore this action was made final.

Amendment Dated October 3, 2002 (a copy of which is attached as Exhibit 7)

In an Amendment to the final Office action dated October 3, 2002, Applicant amended claim 10 and provided arguments to overcome the 35 U.S.C. § 102(b) rejection.

Advisory Action of October 23, 2002 (a copy of which is attached as Exhibit 8)

In the Advisory Action dated October 23, 2002, the Examiner indicated that the proposed Amendment to claim 10 will be entered for purposes of the appeal, and continued to reject claim 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,033,435 to Penn et al.

5. SUMMARY OF INVENTION

The present invention is directed to a method of preparing a bifurcated vessel having a bifurcation, a main vessel, and a side branch vessel, for an interventional procedure.

The method includes providing an elongated catheter 12 having a tracking guide wire lumen 14 for receiving a tracking guide wire 16, the tracking guide wire lumen extending through at least a portion of the catheter. The catheter 12 further includes an integrated guide wire lumen 18 configured

for receiving integrated guide wire 20, the integrated guide wire lumen also extending through at least a portion of the catheter. The tracking guide wire lumen 14 and the integrated guide wire lumen 18 run substantially parallel to each other throughout their lengths, and the tracking guide wire lumen and the integrated guide wire lumen do not move apart with respect to each other as the catheter is manipulated.

The tracking guide wire 16 can be back loaded into the tracking guide wire lumen 14. The catheter 12 is then advanced over the tracking guide wire 16 to a position proximal of the bifurcation in the main vessel 6. Next, the integrated guide wire 20 is advanced through the integrated guide wire lumen 18 and into the side vessel branch 5. The catheter can then be removed from the patient's vasculature in a known rapid-exchange manner or by other appropriate means.

A retaining element, such as a clip 30, is also provided for retaining the tracking guide wire 16 and the integrated guide wire 20. The tracking guide wire 16 and the integrated guide wire 20 can be retained in a spaced apart relationship proximal to the elongated catheter 12, by clipping the wires at their proximal ends outside of the patient's body within the retaining element 30. The retaining element maintains the position of the tracking guide wire 16 relative to the integrated guide wire 20, which helps to prevent wire wrapping, wire crossing, and confusion between wires.

6. ISSUE

Is claim 10 anticipated by Penn et al. '435 under 35 U.S.C. § 102(b)?

7. **GROUPING OF CLAIMS**

Not applicable

8. **ARGUMENT**

In the final Office action dated August 28, 2002 (Exhibit 6), the Examiner rejected claim 10 under 35 U.S.C. § 102(b) as being anticipated by Penn et al. '435 ("the '435 patent"), and stated that the '435 patent teaches a method "providing a retaining element (10) for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to said elongated catheter; and maintaining the position of the tracking guide wire relative to the integrated guide wire with the retaining element (Figure 12)." Subsequently, in the Amendment filed October 3, 2002 (Exhibit 7), claim 10 was amended, and Applicant provided arguments to overcome the 35 U.S.C. § 102(b) rejection. Finally, in the Advisory Action of October 23, 2002 (Exhibit 8), amended claim 10 was entered for purposes of this appeal, and the Examiner continued to reject the claim under § 102(b) as being anticipated by the '435 patent. In the Advisory Action, the Examiner stated that the '435 patent "discloses a retaining element (10) for retaining the tracking and integrated guide wires (185, 190) in a spaced apart relationship proximal to said elongated catheter. Figure 12 in Penn et al clearly shows this spaced apart relationship proximal to the catheter (195, 200)."

However, claim 10 of the current application can not be anticipated by Penn et al. '435, because the Penn et al. reference does not teach every element recited in claim 10. To anticipate a claim, a prior art reference must teach each and every element as set forth in the claim, either expressly or inherently. Verdegaal Bros. V. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987).

Further, "the identical invention must be shown in as complete detail as is contained in the ... claim."

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1990).

For ease of reference, claim 10 is set out immediately below (reference letters have been added), and it is clear that when comparing the claim language to the cited art, that claim 10 is not anticipated.

10. A method of preparing a bifurcated vessel having a bifurcation, a main vessel, and a side branch vessel, for an interventional procedure, comprising the steps of:

[a] providing an elongated catheter;

[b] providing a tracking guide wire and tracking guide wire lumen for receiving the tracking guide wire, the tracking guide wire lumen extending through at least a portion of the catheter;

[c] providing an integrated guide wire and integrated guide wire lumen for receiving the integrated guide wire, the integrated guide wire lumen extending through at least a portion of the catheter;

[d] wherein the tracking guide wire lumen and the integrated guide wire lumen run substantially parallel to each other throughout their lengths, and the tracking guide wire lumen and the integrated guide wire lumen do not move apart with respect to each other;

[e] back loading the tracking guide wire into the tracking guide wire lumen;

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motion

- [f] advancing the catheter over the tracking guide wire to a position proximal of the bifurcation in the main vessel;
- advancement occurs thru lumen to side branch when lumen is placed over.* [g] advancing the integrated guide wire through the integrated guide wire lumen and into the side branch vessel;
- [h] providing a retaining element *line from* [for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to the elongated catheter;]
- [i] maintaining the position of the tracking guide wire relative to the integrated guide wire with the retaining element; and
- [j] removing the catheter from a patient's vasculature.

A. The '435 Patent Does Not Teach a "Retaining Member"

Claim 10 includes elements [h] and [i] which recite respectively "providing a retaining element for retaining the tracking guide wire and the integrated guide wire in a spaced apart relationship proximal to the elongated catheter" and "maintaining the position of the tracking guide wire relative to the integrated guide wire with the retaining element." [emphasis added] The retaining element as claimed is not disclosed explicitly or inherently in the '435 patent, and therefore, claim 10 is not anticipated by the '435 patent.

In rejecting claim 10, the Examiner stated that the retaining element recited in claim 10 was disclosed in the '435 patent as reference numeral 10. Referring to FIG. 12 of the '435 patent, reference numeral 10 designates a stent, not a retaining member as recited in claim 10. It will be shown that the stent 10 in the '435 patent is not a retaining member as claimed in the pending application.

First, a definition of the word “stent” is given at column 1, lines 14-18 of the ‘435 patent, where it states that “[a]s used throughout this specification the term “stent” is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g., a lumen or artery).” It is also stated at column 1, lines 22-24, that “[g]enerally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway.” From these definitions, it is evident that a stent does not function as a retaining member that retains two separate guide wires in a spaced apart relationship proximal to the catheter, which is outside of a patient’s body.

Second, the ‘435 patent discusses the stent delivery system and FIGS. 12-14 at column 11, lines 5 - 64. The stent 10 is described and shown in FIG. 12 as being disposed on a pair of catheters 195, 200. Catheter 195 includes a balloon 205 on its distal end that fills a primary passageway 25 of the stent 10 and substantially fills a secondary passageway 30 of the stent. Catheter 200 includes a balloon 210 on its distal end that also fills the primary passageway 25 of the stent 10 and the balloon 210 substantially fills a secondary passageway 35 of the stent. From this description it is clear that the stent 10 is positioned at the distal ends of the catheters 195, 200 on the balloons 205, 210, and is not in a position to retain the guide wires in a spaced apart relationship proximal to the catheters as set forth in element [h] of claim 10. The retaining member of the present application is positioned outside of the patient’s body where it retains the guide wires in a spaced apart relationship proximal to the catheter to help prevent wire wrapping, crossing, or confusion between wires.

It is also clear from reviewing the ‘435 patent, including FIG. 12, that the catheters 195 and 200 follow a pair of guide wires 185, 190 as the catheters are delivered to a proximal passageway 155,

and therefore the guide wires are disposed within the lumens of the catheters 195, 200 and are not being retained by the stent 10 which is disposed on balloons at the distal end of the catheters. Thus, it is clear that the stent 10 does not maintain the position of one guide wire relative to the other guide wire as set forth in element [i] of claim 10, because the stent does not come into contact with the guide wires 185, 190.

Further, FIG. 12, which is reproduced below, is a cross-section of a bifurcated body passageway 155 showing a stent 10 positioned on the distal end of a pair of catheters 195, 200 following a pair of guide wires 185, 190 through the passageway. Figure 13, also reproduced below, is a cross-section of the bifurcated passageway 155 showing the bifurcated stent 10 in a contracted position.

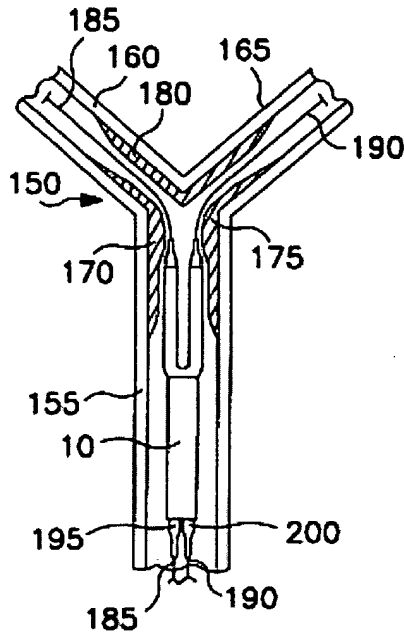


FIG. 12

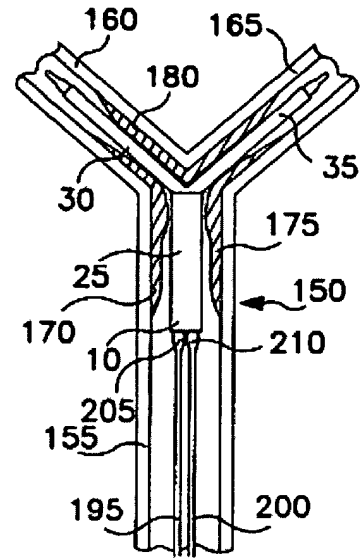


FIG. 13

Referring to FIG. 12, a section on each catheter 195, 200 that is proximal to the stent 10 has been cut away to show the guide wires 185 and 190, however, the catheters actually extend from the bifurcated passageway to the outside of the patient's body where a physician can manipulate the catheters. This is confirmed in FIG. 13, where the stent 10 has been advanced further through the passageway to the bifurcation, and the catheters 195, 200 no longer have a section cut-away, but extend fully through the passageway. Therefore, the actual proximal ends of the catheters are not being shown in FIG. 12, because the proximal ends of the catheters must be outside of the patient's body so the physician can control the positioning of the stent with the catheter. Further, there is no description or figure showing the positioning of the guide wires proximal to the catheters, which would be the positioning of the guide wires outside of the patient's body because the proximal ends of the catheters would be outside of the body. There is also no mention in the '435 patent of any apparatus retaining the guide wires

proximal to the catheters. The '435 patent therefore, does not teach that the stent 10 or any other apparatus retains the guide wires in a spaced apart relationship proximal to the elongated catheter, nor does the stent 10 maintain the position of one guide wire relative to the other guide wire as set forth in elements [h] and [i] of claim 10.

From the above arguments, it is clear that the stent 10 disclosed in the '435 patent is not a retaining member as claimed in the current application, and there is no other apparatus disclosed in the '435 patent that is a retaining member as claimed. Therefore, claim 10 is not anticipated by the '435 patent because elements [h] and [i] as set forth in claim 10 are not disclosed in the '435 patent.

B. The '435 Patent Does Not Teach Element [d] of Claim 10

Element [d] of pending claim 10 recites that "the tracking guide wire lumen and the integrated guide wire lumen run substantially parallel to each other throughout their lengths, and the tracking guide wire lumen and the integrated guide wire lumen do not move apart with respect to each other." This element is also not disclosed explicitly or inherently in the '435 patent. The '435 patent discloses two embodiments of the catheter system, with one embodiment using two separate catheters each with one lumen, and the other embodiment including a single bifurcated catheter. Each embodiment will be discussed separately in the following paragraphs.

The first embodiment of the catheter system is shown in FIGS. 12-13 and is discussed at column 11, lines 18-25 of the '435 patent. This first embodiment includes two catheters 195 and 200, with each catheter having associated with it a balloon 205 and 210, respectively. Balloons 205, 210 substantially fill primary passageway 25 of the bifurcated stent 10, with balloon 205 continuing

through the stent and filling secondary passageway 30 of the stent, and balloon 210 continuing through the stent and filling secondary passageway 35. The stent 10 is bifurcated and the secondary passageways 30, 35 form the bifurcated end of the stent, or put another way, the passageways 30, 35 are in a forked configuration as shown in FIG. 12. Once the stent 10 is positioned at the bifurcated passageway, the bifurcated end of the stent becomes Y-shaped as shown in FIG. 13. Since the catheters/balloons extend through the bifurcated stent, lumens inside each catheter are not substantially parallel to each other throughout their lengths and the lumens do move apart with respect to each other, because each catheter follows a separate passageway 30 or 35 through the bifurcated stent. For the above reasons, this embodiment does not disclose element [d] as recited in claim 10.

The second embodiment for the catheter system is disclosed at column 11, lines 48-52 of the '435 patent, and includes "a single, bifurcated catheter/balloon design which mimics the design of the stent." It is not stated in the '435 patent if the bifurcated catheter has one or two lumens. Claim 10 recites that the catheter has two separate lumens, so if the bifurcated catheter only has one lumen, then claim 10 is not anticipated by the '435 patent for this reason as well. Assuming *arguendo* that the bifurcated catheter does have two lumens, the argument would be similar to the argument involving the first embodiment of the catheter system, that the lumens inside the bifurcated catheter/balloon design also would not be substantially parallel to each other throughout their lengths, and the lumens would move apart with respect to each other. This is because the lumens inside the bifurcated catheter are bifurcated at the distal end of the catheter, so the lumens move apart with respect to each other at

the bifurcation. For these reasons, the bifurcated catheter/balloon design disclosed in the '435 patent also does not include element [d] as set forth in claim 10.

Therefore, since neither embodiment disclosed in the '435 patent teaches element [d] of claim 10, claim 10 can not be anticipated by the '435 reference.

C. The '435 Patent Does Not Teach Element [g] of Claim 10

Element [g] of claim 10 recites that the method of preparing a bifurcated vessel includes "advancing the integrated guide wire through the integrated guide wire lumen and into the side branch vessel." However, the '435 patent does not teach that an integrated guide wire or second guide wire is advanced through the integrated guide wire lumen.

The '435 patent discusses the delivery of the stent to the bifurcated body passageway at column 11, lines 5 - 45. In this section, it is stated that "a pair of guidewires 185, 190 are inserted into proximal passageway 155 such that guidewire 185 enters distal passageway 160 and guidewire 190 enters distal passageway 165." It is further stated that the "stent/catheter/balloon combination is delivered through proximal passageway 155 with the aid of guidewires 185, 190." These sections from the '435 patent describe that both of the guide wires 185, 190 are inserted into the passageway, and then the catheters 195, 200 follow each guide wire through passageway, respectively. In other words, the guide wires 185, 190 are back loaded into the lumens of the catheters 195, 200. No further description or alternative embodiment is discussed in the '435 patent. Therefore, element [g] of claim 10 is absent from the teachings of the '435 patent, because the '435 patent does not disclose that a guide wire is advanced through a lumen of the catheter and into the side branch vessel. On the

contrary, the '435 patent discloses that the catheters are each advanced over the guide wires already positioned in the side branches.

Therefore, without teaching element [g] of claim 10, the '435 patent does not anticipate claim 10.

D. CONCLUSION

Claim 10 is not anticipated by Penn et al. (U.S. Pat. No. 6,033,435) because certain elements recited in claim 10 are not disclosed in Penn et al. In her rejection of claim 10, the Examiner stated that the retaining member cited in claim 10 was disclosed in Penn et al. in the form of a stent 10. However, as shown above, the stent 10 shown in Penn et al. does not retain the guide wires in a spaced apart relationship proximal to the catheter, and the stent also does not maintain the position of one guide wire with respect to a second guide wire. Not only is the stent 10 in Penn et al. not a retaining member, but Penn et al. does not teach a retaining member as recited in claim 10 anywhere in its disclosure. Further, Penn et al. does not disclose that one guide wire lumen runs substantially parallel to a second guide wire lumen throughout their lengths, and that the two guide wire lumens do not move apart with respect to each other. In the two embodiments disclosed in Penn et al., the guide wire lumens move apart from one another and are not substantially parallel throughout their lengths because the lumens inside the catheters are Y-shaped at their distal ends. Yet another element of claim 10 that is not disclosed in Penn et al. is that the integrated guide wire is advanced through the integrated guide wire lumen and into the side branch vessel. As discussed above, Penn et al. only discloses that the

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guide wires first are inserted into the passageway and then the catheters are advanced over the guide wires and through the passageway.

Therefore, since these elements as set forth in claim 10 are not disclosed in Penn et al., claim 10 is not anticipated by Penn et al.

Respectfully submitted,

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LIST OF EXHIBITS

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
1.	Appealed Claim
2.	U.S. Patent No. 6,033,435 to Penn et al.
3.	Preliminary Amendment dated December 12, 2001
4.	First Office Action dated May 9, 20002
5.	Amendment dated August 5, 2002
6.	Final Office Action dated August 28, 2002
7.	Amendment dated October 3, 2002
8.	Advisory Action dated October 28, 2002